



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/545,191	08/10/2005	Lothar Gobel	KCX-1261-PCT-US (64357872)	1365
7590 Dority & Manning, P.A. P.O. BOX 1449 Greenville, SC 29602			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 10/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/545,191	Applicant(s) GOBEL, LOTHAR	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath submitted on 8/10/2005 is objected to because it is not signed by the applicant.

Specification

- The amendments to the specification filed on 6/25/2008 are acknowledged and accepted.
- The disclosure is objected to because of the following informalities: Please update the specification to include the continuity data of the parent applications. Appropriate correction is required.

Drawings

- The replacement drawings filed on 6/25/2008 are acknowledged and accepted. Accordingly, the drawing objections made in the previous office action have been resolved.
- The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “pair of electrodes” and “support” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The 35 USC 112 rejections have been withdrawn in light of the amendments to the claims filed on 6/25/2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-17, 19, 21-24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. (4,850,953). Haber discloses a device (1) for tamponade of body cavities and securement thereto, comprising a flexible tube segment (8) having an inner wall and an outer wall that surrounds an inner space, wherein the tube segment is

Art Unit: 3763

inflatable and configured without any support bodies so that displacement of the tube wall is possible as inflation proceeds, wherein the tube segment comprises two ends (not numbered, clearly shown in Figure 2) which are fastened to a pipe nipple closing element (6) and wherein the ends are joined together fluid tightly through bond (19), wherein the outer wall is thin-walled and expandable and has a wall thickness of a few microns, wherein the tube segment is made of single wall that is invaginated to create the flexible segment, wherein the tube segment *can be* attached to a catheter (claims 6 and 8 only functionally recite the catheter), further comprising a channel (4) for inflating the flexible segment and a flexible channel (36) and valve (44) connected to the channel, wherein a medically active substance can be introduced into the open space (functional limitation), and further comprising a shield (2) and a support ("support" is an extremely broad limitation which can be met by a number of different structures).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (4,850,953). Haber et al. discloses the claimed invention except for using a transparent material or specifically using a material listed in claim 5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use these materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (4,850,953) in view of Elbert et al. (US 2002/0165553). Haber discloses all of the limitations recited in the independent claim but fails to disclose a clamping closure slidably attached to the flexible tube segment. Elbert discloses a clamping closure (20) that is slidably attached to a flexible tube segment (18) of a medical access device that assists in insertion of the device into the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Haber with the clamping closure of Elbert to make a securement device that more easily entered the body.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (4,850,953) in view of Buckholtz et al. (5,409,006). Haber discloses all of the limitations recited in the independent claim but fails to disclose a pressure sensor. Buckholtz discloses that pressure sensors are beneficial in medical access devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the device of Haber with the pressure sensor of Buckholtz to make a securement device that could make sure the appropriate inflation pressure was present.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (4,850,953) in view of Taylor (5,935,107). Haber discloses a gastronomy tube that includes all of the limitations recited in the independent claim but fails to explicitly teach to include an electrode. Taylor discloses that is well known in the gastronomy tube art to include an electrode. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Haber with the electrode of Taylor to make the device of Haber easier to insert into the body.

Response to Arguments

Applicant's arguments filed 6/25/2008 have been fully considered but they are not persuasive.

In response to the applicant's argument that Haber does not meet the limitations of claim 1, the examiner respectfully disagrees. The applicant argues that elements (6, 7) of Haber can be considered "through-passing support bodies" and therefore Haber does meet the limitation of a flexible tube segment that is "configured without through-passing support bodies". The examiner agrees with the applicant's assertion that elements (6, 7) can be considered "through-passing support bodies", but the examiner is interpreting the claim to mean that there are no such bodies between the inner and outer wall of the flexible tube segment. The examiner contends that there are no such bodies within the wall of the defined flexible tube segment (8) as elements (6, 7) lie outside the wall of element (8). For these reasons, the examiner has maintained the

rejection. The examiner suggests reciting that there are no support bodies between the internal area defined by the inner wall.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **THEODORE J. STIGELL** whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763